

510 K SUMMARY

Since all JBC's Proposed polymers are products using the identical polymers as other currently manufactured and distributed dental based resins, it is the pigments that are in question regarding this dental device.

All the polymers were subjected to all the test listed above in the premarket submission for physical characteristics and performances that would be equivalent and/or consistent with the other commercially marketed polymers tested. The non clinical test, simple as they were, displayed results that represented equal performances between the CONTROL and TEST samples.

All pigments/colorants that were used are colorants that have already been allowed for products that fall under the jurisdiction of the FDA for other FD & C or D & C applications, and in some cases, approved for this same dental device.

The physical wearing of dental appliances by family members showed no immediate or short term side affects from any of the new polymers.

I had inquired with the Dental Division of the Food and Drug Administration and asked about obtaining leach testing for each of my products to determine the safeness of the pigments. I was told that the pigments would not leach out the cured methyl methacrylate resin. I was told that if I chose colorants that were already allowed for the Cosmetic industry or for FD&C applications, that I should not have any problems with acceptance.

Any further steps towards the manufacturing or production, await acceptance from the Food and Drug Administration, Center for Devices and Radiological Health, for the manufacturing and marketing of the above mentioned products.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 30 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Priscilla L. Mier
J.B.C and Company
6280 South Valley View Boulevard #122
Las Vegas, Nevada 89118

Re: K002048
Trade Name: JBC Opaque and Glitter
Regulatory Class: II
Product Code: EBI
Dated: June 16, 2000
Received: June 26, 2000

Dear Mr. Mier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

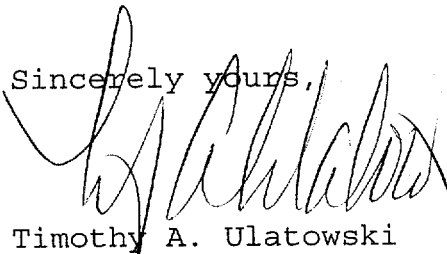
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

COMMERCIAL MARKET:

Because of the restricted nature of all dental resins, the commercial market for my dental products is solely going to be in the dental laboratory/dental office industry.

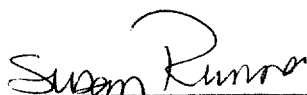
Methyl methacrylate monomer and polymer is used to form a hard acrylic plastic during the fabrication of removable dental appliances.

1. Orthodontic and Dental laboratories:

- a. to be used by qualified dental/orthodontic technicians trained in the fabrication of orthodontic, pedodontic fixed and removable appliances.
- b. trained in the proper use, precautions and hazards of dental resins
- c. the request for these above mentioned dental appliances must come from written appliance prescriptions generated by a licensed dental practitioner.

2. Dental Offices/Clinics

- a. to be used by qualified dental/orthodontic technicians trained in the fabrication of orthodontic, pedodontic fixed and removable appliances.
- b. to be used by qualified dentists/dental assistants trained in the proper use, precautions and hazards of dental resins
- c. to be used under the direct supervision of a licensed dental practitioner.



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

File Number K002048